K061118

MAY 19 2006

OneTouch® UltraMini™ Blood Glucose Monitoring System

510(k) Summary

Submitter

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

510(k) Contact Name: Mary Ellen Holden, Regulatory Project Leader, LifeScan, Inc.
(408) 942-3589 or E-Mail: Mholden@lfsus.jnj.com

510(k) Prepared by: Alison Wilson, Regulatory Specialist, LifeScan Scotland Limited

Device Name

OneTouch® UltraMini™ Blood Glucose Monitoring System
Common name: Glucose test system
Classification:

(1) OneTouch® UltraMini™ Blood Glucose Meters and OneTouch® Ultra® Test Strips are Class II devices (21 CFR § 862.1345)
(2) OneTouch® Ultra® Control Solution is a Class I device (21 CFR § 862.1660)
(3) OneTouch® Lancing Device with AST™ Clear Cap, OneTouch® UltraSoft® Adjustable Blood Sampler with OneTouch® UltraClear® Cap and OneTouch® UltraSoft® Sterile Lancets are Class I (exempt) devices (21 CFR § 878.4800)

System Description

The OneTouch UltraMini Blood Glucose Monitoring System consists of the OneTouch UltraMini Meter, OneTouch Ultra Test Strips (provided separately), OneTouch Ultra Control Solution, OneTouch Lancing Device with AST Clear Cap or OneTouch UltraSoft Blood Sampler with OneTouch UltraClear Cap and OneTouch UltraSoft Sterile Lancets. The predicate OneTouch® Ultra® Meter has been modified to produce the OneTouch UltraMini Meter. The OneTouch Lancing Device with AST Clear Cap is a modification (smaller size) of the existing OneTouch UltraSoft Blood Sampler with OneTouch UltraClear Cap (class I, exempt device). There are no changes to any of the other system testing components compared to the currently marketed product.

Predicate Device

OneTouch Ultra Blood Glucose Monitoring System

Intended Use
The OneTouch UltraMini Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The OneTouch UltraMini System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and/or by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The OneTouch UltraMini Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm or palm.

Comparison to Predicate Device
The modifications to the device encompass meter ergonomic/physical design, electronic/hardware, software/firmware and labeling changes. There has been no change to the intended use, fundamental scientific technology, operating principle, or essential functionality of the device.

Technological Characteristics
There has been no change to the fundamental scientific technology.

Summary of Performance Characteristics
There has been no change to the performance characteristics of the system.

A meter equivalence study demonstrated that the OneTouch UltraMini Blood Glucose Monitoring System and the currently marketed OneTouch Ultra Blood Glucose Monitoring System are substantially equivalent.

Design Verification (including software verification and validation) testing confirmed that the performance, safety and effectiveness of the OneTouch UltraMini Blood Glucose Monitoring System were equivalent with that of the predicate device.

The modified meter was tested in accordance with ISO 15197:2003(E) including System Accuracy, Clinical Accuracy, and Consumer Evaluation to assess ease of use (human factors and user acceptance). In addition, reading level assessment of the product labeling was conducted and validated for comprehension.

Conclusion
The modified OneTouch UltraMini Blood Glucose Monitoring System is substantially equivalent to the predicate OneTouch Ultra Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 19 2006

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312
Attn: Mary Ellen Holden, Regulatory Project Leader

Re: k061118
Trade/Device Name: One-Touch® UltraMini™ Blood Glucose Monitoring System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW
Dated: April 20, 2006
Received: April 21, 2006

Dear Ms. Holden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K061118

Device Name: OneTouch® UltraMini™ Blood Glucose Monitoring System

Indications For Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) (AND/OR) Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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